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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/466,387	12/17/1999	PAT L. GORDON	3581/004	1111

7590

12/23/2003

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NEW YORK, NY 100201104

EXAMINER

SCHAETZLE, KENNEDY

ART UNIT	PAPER NUMBER
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3762

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DATE MAILED: 12/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

09/466,387

Applicant(s)

GORDON, PAT L.

Examiner

Kennedy Schaetzle

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-67 is/are pending in the application.
- 4a) Of the above claim(s) 39-67 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-9, 15, 17-21, 24, 26, 28 and 35-38 is/are rejected.
- 7) ☒ Claim(s) 6, 10-14, 16, 22, 23, 25, 27 and 29-34 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 February 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5, 10. 6) ☐ Other: ____.

DETAILED ACTION
Election/Restrictions

1. Applicant's election of Group I (claims 1-38) in Paper No. 12 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Concerning the applicant's statement in paper number 12 regarding the examiner's assertion that certain embodiments were not considered to be patentably distinct (see marked paragraph 4 of the Office Action mailed as paper no. 11), the applicant appears to be confusing the term "patentable" with the term "patentably distinct." The two terms have completely different meanings, with the term "patentable" relating to an invention that is unobvious and/or novel as determined by an analysis of the prior art, and the term "patentably distinct" relating to embodiments that can be supported by separate patents. For example, the wheel and gunpowder are certainly not *patentable* as both have been invented long ago, and yet the two are most certainly *patentably distinct* because they are not obvious variants of one another and can therefore support separate patents without invoking the issue of obviousness-type double patenting. Lacking any statement by the applicant to the contrary and considering the applicant's election of all the embodiments, the examiner will consider the embodiments discussed in paragraph 4 of the previous Office Action to be obvious variants of one another (i.e., not patentably distinct).

Specification

3. The disclosure is objected to because of the following informalities: There is no discussion of Fig. 10 (see formal drawings received February 23, 2000) in either the "Brief Description of the Drawings" or the "Detailed Description of the Invention" sections; and the missing text on page 9 of the disclosure must be supplied.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claim 37 is rejected under 35 U.S.C. 102(b) as being anticipated by Baker, Jr. (Pat. No. 5,222,494).

Regarding claim 37, Baker, Jr. discloses a neurostimulator comprising a current sensor to detect the current applied to the tissue being stimulated (see col. 2, lines 9-15), and circuitry configured to compare the current with a predetermined current threshold (see col. 2, lines 15-16) and to adjust the voltage-controlled pulse if the current is found to meet the predetermined current threshold by such detection, such that the current does not exceed the predetermined current threshold (see col. 2, lines 16-19). The examiner considers a current that exceeds a predetermined current threshold to be a current that meets a predetermined current threshold. By analogy, a full glass of water can be said to meet the threshold of being at least half-full. The examiner also notes the applicant's comments on page 15, lines 17-28 wherein feedback may be used to maintain the voltage/current at the limit, slightly below the limit, or prevent the voltage/current from exceeding the limit, as deemed appropriate by one skilled in the art.

Addressing the preamble of the claim and its reference to stimulation of the gastrointestinal tract, statements of intended use will have no effect in saliently distinguishing over the apparatus of Baker, Jr.. The neurostimulator of Baker, Jr. is capable of stimulating the gastrointestinal tract.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-4, 15, 17-21, 35, 36 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baker, Jr. (Pat. No. 5,222,494).

Regarding claims 1 and 19, as stated in the previous Office Action, the examiner considers the species involving the application of a current-controlled pulse to be patentably indistinct from the species involving the application of a voltage-controlled pulse. Those of ordinary skill in the neuromuscular stimulation arts recognizing voltage and current to be two well-known related parameters useful in characterizing and modifying pulse energy output, would have seen the obviousness of manipulating one or the other as a means to control stimulation.

Concerning claims 2 and 3, Baker, Jr. teaches that current, frequency, pulse width, etc. of the voltage-controlled output pulse may be programmable and that parameters may be programmed into the stimulator via telemetry (col. 4, line 67- col. 5, line 14). Since the particular output current desired and concomitantly the voltage threshold employed to maintain such an output current would be dependent upon the condition of the patient, the location of stimulation and the desired effect, those artisans of ordinary skill in the art would have seen the obviousness of providing for an adjustable voltage threshold to allow for flexibility of treatment. Allowing for adjustment of threshold parameters when dealing with implantable medical devices is old and well-known, since it allows one to tailor the device to the particular individual receiving the implant. A related comment applies to claim 20.

Regarding claim 4, note col. 3, lines 62-66. Again, whether one has a set of voltage thresholds or a set of current thresholds would have been considered a matter of obvious design by those of ordinary skill in the art. A related comment applies to claim 21.

Concerning claim 15, by virtue of the fact that the device of Baker, Jr. is programmable, it is necessary for such a device to have memory. The use of memory such as RAM in conjunction with microprocessor and logic/control circuitry is old in the art and the examiner takes Official Notice to this effect. The storage of an event

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characterized by the voltage being found to meet the predetermined threshold is considered by the examiner to be merely a statement of intended use for the memory since the claims are directed not to the method of storage, but to the apparatus used for storage.

Regarding claims 17 and 18, note col. 4, lines 4-26, keeping in mind the examiner's comments pertaining to the use of current-controlled or voltage-controlled pulses. Related comments apply to claims 35 and 36.

Parallel comments made in the rejection of claim 37 apply to method claims 19 and 38. In addition, Baker, Jr. asserts that the teachings presented in his disclosure apply to any implantable medical device (col. 1, lines 21-24). Clearly then, such teachings apply to neuromuscular stimulators of the gastrointestinal type. To therefore employ the teachings of Baker, Jr. in a method of stimulating the gastrointestinal tract in order to take advantage of the improvements in energy efficiency outlined by Baker, Jr., would have been considered obvious by those artisans of ordinary skill.

8. Claims 5, 7-9, 24, 26 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baker, Jr. in view of Padjen et al. (Pat. No. 4,719,922).

Baker, Jr. does not discuss circuitry for calculating electrode resistance. Padjen et al., however, disclose a related neurostimulator device that monitors the electrode resistance in order to determine the quality of electrode connection to tissue (note col. 4, lines 33-50). Such a technique is well-known by those of ordinary skill in the stimulator arts as a means to enhance device efficiency and patient safety. An electrode that is not properly connected to the tissue site, may result in inadequate stimulation to the patient and therefore waste energy. Since Baker, Jr. is concerned with maximizing energy efficiency and since the detection of electrode impedance for the purposes of enhancing energy efficiency are well-documented, those artisans of ordinary skill in the art would have seen the obviousness of monitoring electrode resistance.

Concerning claim 7, the electrode resistance is considered associated with the current level of the current/voltage-controlled pulse by Ohm's law.

With reference to claim 8, by virtue of the fact that the device of Baker, Jr. is programmable, it is necessary for such a device to have memory. The use of memory such as RAM in conjunction with microprocessor and logic/control circuitry is old in the art and the examiner takes Official Notice to this effect. The storage of electrode resistance and associated current level is considered by the examiner to be merely a statement of intended use for the memory since the claims are directed not to the method of storage, but to the apparatus used for storage.

Regarding claim 9 and claims with similar limitations, Baker, Jr. does not explicitly disclose the use of a display. Baker, Jr. does however disclose that components of the system may include a computer for monitoring signals (note the text abridging cols. 4 and 5). The examiner takes Official Notice that computers have displays. The examiner considers the reference to the display of electrode resistance and associated current level to be merely a statement of intended use for the display, and thus insufficient to saliently distinguish over the apparatus defined by Baker, Jr. and Padjen et al.. In any event –and specifically referring to method claim 28-- Padjen et al. disclose the use of a display in a similar stimulator apparatus and state that electrode fault indications and current intensity levels may be monitored (col. 3, lines 20-35). Since the measured electrical resistance is an indicator of electrode fault (e.g., a high impedance value may indicate that the electrode is not properly contacting the tissue), and since the current intensity is an important parameter to know for those applying treatment, those of ordinary skill in the art would have considered the display of resistance and associated current levels a matter of obvious design.

Allowable Subject Matter

9. Claims 6, 10-14, 16, 22, 23, 25, 27 and 29-34 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Regarding claim 6 and claims with similar limitations, the prior art of record does not appear to disclose configuring the circuitry to determine an increment of adjustment of voltage based on the electrode resistance.

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Regarding claim 10 and claims with similar limitations, the prior art of record does not appear to disclose a teaching for modifying the circuitry of Baker, Jr. to calculate capacitance of tissue.

Regarding claim 16, the prior art of record does not appear to disclose configuring the stimulator to determine and store the recited time value.

Regarding claim 22, there is no suggestion to modify Baker, Jr. to prepare the set of voltage thresholds in the manner set forth. Said thresholds appear to be predetermined.

Regarding claim 27, there is no teaching in the prior art of record for modifying the method of Baker, Jr. to store the electrode resistance and the associated current level in a database.

Conclusion

10. The examiner wishes to notify the applicant that while it would appear from the case filewrapper that four IDS documents have been received (paper nos. 5-7 and 10), the file appears to only contain the IDS documents associated with paper nos. 5 and 10. Clarification is requested to confirm or deny submission of these documents so that the file may be complete. If the applicant would like consideration of the IDS documents submitted May 1, 2000 (paper no. 6) and September 15, 2000 (paper no. 7), a copy of these statements should be submitted in response to the present Office Action.

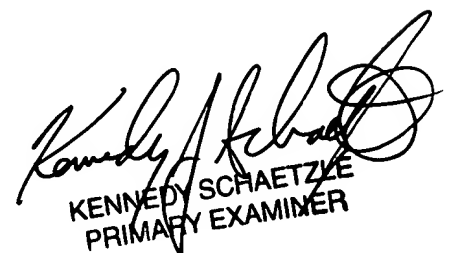
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 703 308-2211. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703 872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0858.

KJS

December 11, 2003


KENNEDY SCHAETZLE
PRIMARY EXAMINER